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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,759	07/17/2003	Manfred Galle	029300.52497US	9152

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,759	GALLE ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 – 13 in the reply filed on September 30, 2004 is acknowledged. The traversal is on the grounds that the inventions are not independent since the method of group II requires administering the composition of group I. This is not found persuasive because as stated in the previous office action, other materially different composition could be used in a method for treating maldigestion, for example lactobacillus. The inventions of groups I and II are distinct and separate inventions, as they are classified separately and require different searches. While the searches of the groups may overlap, it is pointed out that an overlapping search is not a coextensive search. Thus, a reference that would anticipate the invention of one group may not anticipate or even make obvious the invention of the other group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14 – 18 are withdrawn as being drawn to a non-elected invention. Claims 1 – 13 have been considered on merits.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sipos (US 5750104 A) in view of Ogawa et al. (US 6013680 A).

Applicant claims a composition comprising a concentrated lipase of Phizopus delemar, a neutral protease of Aspergillus mellus, and an amylase of Aspergillus oryae. The lipase has a specific activity of 1,800,000 FIP units/gram; the protease has a specific activity of 7,500 FIP units/gram; and the protease has a pH optimum of 6 – 8. Applicant claims a pharmaceutical composition comprising the enzyme mixture and at least one carrier or adjuvant. The composition is in a form selected from a powder, pellets, microspheres, capsules, sachets, tablets, liquid suspension or liquid solution; at least one of the enzymes are individually pelleted; or is film coated with an enteric layer. Specifically the protease is pelleted and film coated with an enteric layer; the lipase is pelleted and film coated; or alternatively the protease and lipase are pelleted and film coated. The compositions comprises the lipase : amylase : protease ratio at 50

– 500FIP lipase : 40 – 120 FIP amylase : 1 FIP protease; and each dose contains at least 10,000 FIP units lipase, 8000 FIP units amylase and 200 FIP units protease.

Sipos teaches pharmaceutical compositions for treating digestive disorders comprising protease, lipase (3.1.1.3, lipase of Rhizopus delemar) and amylase (3.2.1.1, amylase of Aspergillus oryzae) (col.6 line 11-21). The compositions and ingredients are formed into microspheres or microtablets, contain suitable carriers and/or adjuvants (examples), and are individually coated with an enteric coating (col.5 line 62-67, col.7 line 21-30). Sipos teaches the compositions are buffered to provide an optimum pH of 7 – 10 (col.6 line 50-51).

Sipos does not teach the compositions wherein the protease is a neutral protease of Aspergillu melleus, wherein its optimum pH is 6 - 8. However, Ogawa teaches compositions for treating digestive disorders comprising the digestive protease Prozyme 6 (neutral protease of Aspergillus melleus) (abstract, col.4 line 1-29). As evidenced by Ogawa, neutral protease of Aspergillus melleus was a well-known and used protease in the art for compositions that treat digestive disorders. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use neutral protease of Aspergillus melleus as the protease in the composition of Sipos, since it was well-known and used for its claimed purpose, as evidenced by Ogawa. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Ogawa to use neutral protease of Aspergillus melleus as the protease in the composition of Sipos, with a reasonable expectation for successfully obtaining an effective composition for treating digestive disorders. Although the references do not specifically teach that the protease has an optimum pH of 6 – 8, the protease of Ogawa is the same as the claimed

protease. Therefore, the protease of Ogawa must also have the same characteristics of the claimed protease, specifically an optimum pH of 6 – 8.

Sipos does not teach the composition wherein the lipase and protease have the claimed specific activities, or wherein the composition comprises the claimed ratios or amounts of enzymes. However, Sipos does teach the compositions with varying activities of lipase, amylase and protease. Specifically 4000 – 8000 USP lipase; 25,000 – 40,000 USP amylase; and 25,000 – 45,000 USP protease (examples 2,3). Sipos further teaches the compositions comprising 10 – 70% enzymes with varying amounts of each enzyme (examples) and that the amounts and dosages are variable and can be optimized according to the condition, patient and practitioner (col.15 line 39-48). In addition, Ogawa teaches the compositions comprise amounts of protease sufficient to exert digestive activity; specifically at least 200 FIP units or 15,000 units (col.4 line 32-56) and that the compositions can be changed and/or modified by one of ordinary skill in the art (col.13 line 7-11).

It is well known in the art that enzyme activity is determined by the quantity of substrate transformed or product formed per unit of time (International Commission of Pharmaceutical Enzymes F.I.P). Since such activities are dependent on a number of experimental conditions (pH, temperature, presence of inhibitors/activators), one of ordinary skill in the art would know to optimize such conditions to attain a desired activity. As evidenced by Sipos and Ogawa, the specific activities of the instant enzymes in compositions for treating digestive disorders were routinely variable. As such, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize specific activities, dosages and amounts of each enzyme as a matter of routine experimentation. Moreover, at the time of the

claimed invention, one of ordinary skill in the art would have been motivated by Sipos, Ogawa and standard practice, to optimize the specific activities, amounts and ratios of the instant enzymes with a reasonable expectation for successfully obtaining a composition effective for treating digestive disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
December 1, 2004
AU 1651